

WHAT IS CLAIMED IS:

1. A method for aerosolizing a pharmaceutical formulation, the method comprising:
 - preventing respiratory gases from flowing to the lungs when attempting to inhale, and then abruptly permitting respiratory gases to flow to the lungs; and
 - using the flow of respiratory gases to extract a pharmaceutical formulation from a receptacle and to place the pharmaceutical formulation within the flow of respiratory gases to form an aerosol.
2. A method as in claim 1, further comprising limiting the flow of respiratory gases to a rate that is less than a certain rate for a certain time.
3. A method as in claim 2, wherein the rate is less than about 15 L/min and the time is in the range from about 0.5 seconds to about 5 seconds.
4. A method as in claim 2, wherein the rate is less than about 8 L/min and the time is in the range from about 0.5 seconds to about 5 seconds.
5. A method as in claim 2, wherein the certain rate permits an inhaled volume that is in the range from about 125 mL to about 1.25L
6. A method as in claim 1, wherein the flow preventing step further comprises placing a valve within an airway leading to the lungs and opening the valve to permit respiratory gases to flow to the lungs.
7. A method as in claim 6, further comprising opening the valve when a threshold actuating vacuum caused by the attempted inhalation is exceeded.
8. A method as in claim 7, wherein the threshold actuating vacuum is in a range from about 20 cm H₂O to about 60 cm H₂O.

9. A method as in claim 6, wherein the valve comprises an occlusion member having an opening, and a pull through member that is pulled through the opening when the threshold actuating vacuum is produced.

10. A method as in claim 9, wherein the occlusion member comprises an elastomeric membrane, and wherein the pull through member comprises a ball.

11. A method as in claim 2, wherein the flow limiting step comprises providing feedback when an excessive flow rate is produced to permit a user to adjust their inhalation rate.

12. A method as in claim 2, wherein the flow limiting step comprises regulating the size of an airway leading to the lungs.

13. A method as in claim 12, further comprising regulating the size of the airway with an elastomeric duckbill valve.

14. A method as in claim 12, further comprising regulating the size of the airway with a spring biased ball that is disposed within a tapered opening such that the ball is drawn into the opening as the flow rate increases.

15. A method as in claim 12, further comprising regulating the size of the airway to permit an increased flow rate after the certain time has lapsed.

16. A method as in claim 2, further comprising providing another airway to permit an increase flow of gases to the lungs after the certain time has lapsed.

17. A method as in claim 1, wherein the pharmaceutical formulation comprises a powdered medicament, and further comprising using the flow of respiratory gases to deagglomerate the extracted powder.

18. A method for administering a pharmaceutical formulation, the method comprising:

providing an inhalation device comprising a housing having first and second openings to ambient air and a mouthpiece at one of said openings;

preventing respiratory gases from flowing to the lungs when attempting to inhale through said mouthpiece;

permitting the flow of a first predetermined volume of respiratory gases to the lungs, said first volume being sufficient to transport substantially all of a unit dose of a pharmaceutical formulation contained within the inhalation device out of the device and into the respiratory tract of a patient; and

permitting a second volume of respiratory gases to flow to the lungs.

19. A method as in claim 18 wherein the flow of respiratory gases is prevented by providing the device with a valve between said openings.

20. A method according to claim 19 wherein the flow of respiratory gases is permitted by opening said valve when a threshold actuating vacuum by the attempted inhalation is exceeded.

21. A method according to claim 20 wherein said vacuum is within 20 – 60 cm H₂O.

22. A method as in claim 18 wherein said first predetermined volume of respiratory gases is in the range from 125 mL to 1.25 L.

23. A method as in claim 18 further comprising regulating the flow of respiratory gases at a first flow rate until said first predetermined volume of respiratory gases flows through said device.

24. A method according to claim 23 wherein the first flow rate is less than 15 L/min.

25. A method according to claim 23 further comprising regulating the flow of said second volume of respiratory gases at a second flow rate.

26. An aerosolization device, comprising:

a housing defining an airway;
a coupling mechanism adapted to couple a receptacle containing a pharmaceutical formulation to the airway; and
a valve to prevent respiratory gases from flowing through the airway until a threshold actuating vacuum is exceeded at which time the valve opens to permit respiratory gases to flow through the airway and to extract the pharmaceutical formulation from the receptacle to form an aerosol.

27. A device as in claim 26, further comprising a regulation system to regulate the flow of respiratory gases through the airway to a certain rate.

28. A device as in claim 27, wherein the regulation system is configured to limit the flow to a rate that is less than about 15L/min for a certain time or a certain inhaled volume.

29. A device as in claim 27, wherein the regulation system comprises a feedback mechanism to provide information on the rate of flow of the respiratory gases.

30. A device as in claim 29, wherein the feedback mechanism comprises a whistle in communication with the airway.

31. A device as in claim 27, wherein the regulation system comprises a restrictive member disposed in the airway, the restrictive member defining an orifice sized to limit the flow of respiratory gases through the airway.

32. A device as in claim 27, wherein the regulation system comprises a restriction mechanism to limit the size of the airway.

33. A device as in claim 32, wherein the restriction mechanism comprises an elastomeric duckbill valve that closes as the flow rate of the respiratory gases increases.

34. A device as in claim 32, wherein the restriction mechanism comprises a spring biased ball that is drawn into a tapered opening as the flow rate of the respiratory gases increases.

35. A device as in claim 32, wherein the restriction mechanism is adjustable to vary the rate of flow of respiratory gases through the airway.

36. A device as in claim 35, wherein the regulation system further comprises a control system to adjust the restriction mechanism.

37. A device as in claim 36, wherein the control system is configured to limit the flow to the certain rate for a certain time or inhaled volume and then to adjust the restriction mechanism to permit an increased flow of respiratory gases through the airway.

38. A device as in claim 28, further comprising a flow integrator that is configured to open another airway in the housing after a certain time or inhaled volume.

39. A device as in claim 26, wherein the valve comprises an occlusion member having an opening, and a pull through member that is pulled through the opening when the threshold actuating vacuum is produced.

40. A device as in claim 39, wherein the occlusion member comprises an elastomeric membrane, and wherein the pull through member comprises a ball.

41. A device as in claim 26, wherein the threshold actuating vacuum of the valve is in a range from about 20 cm H₂O to about 60 cm H₂O.

42. A device as in claim 26, further comprising a deagglomeration mechanism disposed in the airway downstream of the receptacle to deagglomerate the extracted pharmaceutical formulation.

43. A device as in claim 26, wherein the valve is adapted to be disposed within the receptacle.

44. An aerosolization system comprising:
a receptacle comprising a chamber having a pharmaceutical formulation and a threshold valve;
a housing defining an airway; and
a coupling mechanism to position the valve across the airway and to place the pharmaceutical formulation in fluid communication with the airway;
wherein the threshold valve is configured to open when a threshold actuating vacuum is exceeded to permit respiratory gases to flow through the airway and extract the pharmaceutical formulation from the chamber to form an aerosol.

45. A system as in claim 44, wherein the pharmaceutical formulation comprises a powdered medicament.

46. A system as in claim 44, wherein the pharmaceutical formulation comprises a liquid medicament.

47. A system as in claim 44, further comprising a regulation system to regulate the flow of respiratory gases through the airway.

48. A receptacle comprising:
a receptacle body defining a cavity enclosed by a penetrable access lid; and
a threshold valve coupled to the receptacle body.

49. A receptacle as in claim 48; wherein the threshold valve is configured to open when experiencing a vacuum of at least about 40 cm H₂O.

50. An aerosolization device, comprising:
a housing having a mouthpiece;
an aerosolization mechanism disposed in the housing, wherein the aerosolization mechanism is adapted to aerosolize a powdered medicament when a user inhales from the mouthpiece; and

a positioning system that is adapted to facilitate proper positioning of a user's mouth over the mouthpiece prior to inhalation.

51. A device as in claim 50, wherein the positioning system comprises at least one hole in a side of the mouthpiece over which the user must position the mouth to produce a vacuum sufficient to cause aerosolization of the powdered medicament.

52. A device as in claim 50, wherein the positioning system comprises a positioning landmark disposed on the mouthpiece that is interactable with a physiological feature of the user.